

REMARKS

1. STATUS OF CLAIMS

Claims 60, 61, 67, 68, 71, and 72 are pending in the application.

Applicants have amended claims 60 and 61 to clarify that the substrate “mass” recited in the claim is a “**mass of material**”. Support for the amendment is found in the specification as filed at paragraph [0070]¹ wherein the substrate is specifically defined.

2. THE OFFICE ACTION OF MARCH 4, 2009

Rejections

The Examiner, in a Final Office Action mailed August 25, 2009, rejected all of the pending claims in the application.

A. Claim 61 was rejected under 35 U.S.C. § 102(b) as being anticipated by Schafer et al. U.S. 4,617,186 (“Schafer”).

B. Claims 61 and 71 were rejected under 35 U.S.C. § 102(b) as being anticipated by Somasundaran et al. U.S. 5,476,660 (“Somasundaran”).

C. Claims 61 and 70-72 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Batich et al. U.S. Appl. 2002/0177828 (“Batich”) in view of Ward et al. U.S. 5,575,993 (“Ward”).

D. Claims 60 and 64-68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Batich et al. U.S. Appl. 2002/0177828 (“Batich”) in view of Schoenfeldt et al. U.S. Appl. 2002/0172708 (“Schoenfeldt”) and further in view of Voorhees et al. U.S. 2004/0235950 (“Voorhees”).

3. ARGUMENTS AGAINST EXAMINER’S REJECTIONS

Applicants respectfully traverse the Examiner’s rejections of claims 60, 61, 67, 68, 71, and 72 and request reconsideration and withdrawal of the rejections based on the above amendments and the following remarks.

A. REJECTION OF CLAIM 61 UNDER 35 U.S.C. § 102(b) AS BEING ANTICIPATED BY SCHAFER.

The Examiner asserts that Schafer teaches a sustained release drug delivery system which utilizes cationic polymeric quaternary ammonium compounds in combination with anionic drugs. The Examiner asserts that Schafer teaches that the drug delivery system is a viscous polymer system which is within the scope of a flexible mass. The Examiner also asserts that the claimed substrate is not

¹ Citations herein to published patent applications are to the numbered paragraphs of the printed version.

necessarily a separate component from the polymer and drug. Applicants respectfully disagree.

Schafer discloses polyquats as drug delivery systems for anionic drugs [col 1, ln 61 to col 2, ln 7]. The polyquats tightly bind anionic drugs through salt formation [col 2, ln 61-68]. The drug delivery system has bioadhesive properties – binding to eukaryotic cells or human tissue [col 1, ln 61 to col 2, ln 7] and human epithelial cells and fibroblast on collagenated supports in tissue cultures [col 2, ln 46-60].

Schafer does not disclose the binding of polyquats to “woven or nonwoven, solid, or flexible mass of material” as recited in claim 61. The “viscous polymer system” disclosed by Schafer is the polyquat and the drug. The viscous polymer system is not non-leachably attached to a separate substrate. Applicants point out that claim 61 recites, in pertinent part, “a material comprising a substrate, ...and further comprising a polyionic polymer...**non-leachably bound** to said substrate, and further comprising a sufficient quantity of an anionic antibiotic, analgesic, anti-inflammatory, or a combination thereof, ionically associated with said polyionic polymer...” [Emphasis added].

Applicants assert that the Examiner has mischaracterized the relationship between the components of the material of claim 61. The material comprises the substrate, the polyionic polymer **and** an anionic antibiotic, analgesic, anti-inflammatory, or a combination thereof. Applicants assert that each of these components of the material is a separate component that is non-leachably bound or ionically associated with other components within the material. Applicants have specifically defined substrate and exemplified what was intended as a “mass of material” within paragraph [0070] of the specification.

Applicants assert that Schafer does not disclose each and every limitation of the method recited in claim 61. Therefore, Schafer cannot anticipate the claim. Applicants respectfully request the Examiner to withdraw the rejection and allow claim 61.

B. REJECTION OF CLAIMS 61 AND 71 UNDER 35 U.S.C. § 102(b) AS BEING ANTICIPATED BY SOMASUNDARAN.

The Examiner asserts that Somasundaran teaches deposition of anionic active agents on to surfaces such as human skin, hair, oral surface and fabrics using carrier particles containing cationic polymers, preferably polyquats. Furthermore, the Examiner asserts that the entire particle is within the meaning of the claimed substrate.

Applicants respectfully disagree.

While Somasundaran does teach the deposition of anionic active agents on surfaces using carrier particles, Somasundaran also teaches that the deposition occurs in a way that the active stays on the surface (substrate) after the compositions containing the active have been rinsed off [col 2, ln 6-9]. Applicants

assert that Somasundaran is teaching that carrier particles are NOT bound to the surface (substrate) that the actives are being attached to. More importantly, Somasundaran does not teach that the carrier particles (such as Merquat) are “non-leachably bound to said substrate” as recited in Applicants’ claim 61.

Somasundaran uses the polymer/active composition to apply the active to a surface. Somasundaran does not use the polymer/active composition to apply to a substrate which is then used to treat a separate surface. Applicants assert that Somasundaran does not teach a treatment method using “a material comprising a substrate, a polyionic polymer non-leachably bound to the substrate, and an anionic antibiotic, analgesic, anti-inflammatory, or combination thereof” as recited in claim 61. Somasundaran does not teach non-leachably bonding a polyionic polymer to a substrate, ionically associating an active agent with the substrate and polyionic polymer to generate a material, wherein the material is used in a method for treating conditions.

Applicants also assert that Somasundaran does not disclose each and every limitation of the method recited in claim 61. Therefore, Somasundaran cannot anticipate the claim. Claim 71 depends from claim 61 and incorporates the limitations of claim 61. Therefore, claim 71 is also not anticipated by Somasundaran. Applicants respectfully request the Examiner to withdraw the rejection and allow claims 61 and 71.

C. REJECTION OF CLAIMS 61 and 70-72 UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER BATICH IN VIEW OF WARD.

Applicants respectfully traverse the rejection and assert that Batich, in view of Ward, does not make claims 61, 71 and 72 obvious to one of ordinary skill in the art. The rejection is moot with respect to claim 70 because it is now canceled. Applicants reassert the arguments presented in their June 3, 2008, December 12, 2008, and June 4, 2009 responses.

The Examiner was unclear of the relevance of Applicants’ assertion that the secondary reference Ward does not teach or suggest an anionic antimicrobial compound in association with a quaternary ammonium polymer to achieve extended release. Applicants assert that one of ordinary skill in the art would not have a reason to combine Ward with Batich to develop the claimed subject matter of the invention. One of ordinary skill in the art would not look to a patent that describes leachable polymers (Ward) as a basis for an invention claiming non-leachable polymers (Applicants).

D. REJECTION OF CLAIMS 60 and 64-68 UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER BATICH IN VIEW OF SCHOENFELDT AND VOORHEES.

Applicants respectfully traverse the rejection and submit that Batich, in view of Schoenfeldt and Voorhees, does not make amended claim 60 and claims, 67 and

68 obvious to one of ordinary skill in the art. The rejection is moot with respect to claims 64-66 because they are now canceled. Applicants reassert the arguments presented in their June 3, 2008, December 12, 2008, and June 4, 2009 responses.

The Examiner asserts that Schoenfeldt recites a cationic amine which is an ammonium ion which includes protonated substituted amines. Applicants assert that quaternary ammonium compound is NOT a protonated substituted amine. The methods of preparing and using quaternary ammonium salts are different than the methods used for protonated substituted amines. The chemistry of primary ammonium salts is not the same as the chemistry of a quaternary ammonium salt. One of ordinary skill in the art cannot prepare a quaternary ammonium compound by protonating an amine precursor. Applicants further assert that one of ordinary skill in the art would not have a reasonable expectation of success in combining Schoenfeldt and Batich because the chemistry between the two references is not directly transferable.

Therefore, Applicants respectfully submit that the combination of Batich, Schoenfeldt, and Voorhees does not make obvious the invention as claimed. Applicants respectfully request the Examiner to withdraw the obviousness rejection of claims 60, 67, and 68 and allow the claims as currently amended.

CONCLUSION

Applicants respectfully traverse all of the rejections. Claim 61 is not anticipated by either Schafer or Somasundaran because the prior art does not disclose each and every element of the claim. Claim 71 which depends from claim 61 is also not anticipated. Claims 60 and 67-68 are not made obvious to one of ordinary skill in the art by the disclosures of Batich, Schoenfeldt, and Voorhees as described above. Claims 61 and 71-72 are not made obvious to one of ordinary skill in the art by the disclosures of Batich, and Ward as described above.

For the foregoing reasons, Applicants submit that the claims presented herewith are patentable over the prior art of record and respectfully solicit prompt action thereon. If any questions remain, the Examiner is invited to phone the undersigned attorneys.

Respectfully submitted:

February 24, 2010

/s. m. p. m./

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